# MAJOR ARTICLE







# Engagement in Preexposure Prophylaxis Care at 1 Year Among Men Who Have Sex With Men Enrolled in the French ANRS PREVENIR Cohort Study

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*Background.* We evaluated 1-year engagement in pre-exposure prophylaxis (PrEP) care and associated factors among gay, bisexual, and other men who have sex with men (GBMSM) in a large cohort of oral PrEP users in the Paris region, France.

*Methods.* We included in this analysis cisgender GBMSM enrolled in the ANRS PREVENIR cohort study from 3 May 2017 to 28 February 2019. We categorized 1-year PrEP engagement into 4 categories: high (consistent visits, attendance, and prescription refills at months 3, 6, 9, and 12), low (missed visits or no prescription refills), disengagement (PrEP discontinuation), and lost to follow-up. We used a logistic regression model to identify sociodemographic and behavioral factors associated with high engagement in PrEP care.

**Results.** Of 3211 participants, 2685 GBMSM were included in the analysis. At enrollment, participants had a median age of 36 years, with 88% born in Europe and 52.4% already undergoing PrEP. At month 12, 1612 (60.0%) participants met the high engagement definition, 438 (16.3%) exhibited low engagement, 459 (17.1%) disengaged from PrEP care, and 176 (6.6%) were lost to follow-up. In multivariable analysis, high engagement in PrEP care at 1 year was associated with older age (P < .001), being born in Europe (P = .01), having a higher education level (P = .05), already undergoing PrEP at enrollment (P < .001), having a bacterial sexually transmitted infection in the prior year (P = .01), earlier enrollment in the study (P = .04), and using PrEP daily or switching between PrEP regimens within the first year (P < .001).

**Conclusions.** Younger GBMSM, those born outside Europe, and those who were PrEP naive had lower engagement rates in the cohort, requiring tailored support.

**Keywords.** on demand; persistence; PrEP; retention; tenofovir.

Preexposure prophylaxis (PrEP) of HIV is a highly effective biomedical intervention that has revolutionized the HIV prevention field over the last decade. In 2021, 144 countries have

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adopted the World Health Organization recommendations on oral PrEP in their national guidelines [1], and large-scale PrEP rollout, as part of a combination prevention approach, has contributed to reducing HIV incidence at the population level in diverse settings [2, 3]. As the number of individuals initiating PrEP continues to rise, reaching an estimated 6 million worldwide in 2024 [4], addressing challenges related to adherence and persistence has become crucial to ensure the longterm success of PrEP [5]. Although PrEP is not intended to be a lifelong treatment and can be stopped during periods of low perceived risk, PrEP interruptions may result in an increased risk of HIV infection, which can significantly reduce the effectiveness of PrEP in real-world settings [6-8]. Early discontinuations remain common among PrEP users. A recent meta-analysis of 59 studies estimated that 41% of users discontinued PrEP within 6 months (95% CI, 18.8%-63.5%), with significant variations across study design, geographic regions, population, or PrEP regimen [6]. Studies conducted in

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Europe reported a lower rate of PrEP discontinuation within 6 months (17%) as compared with other regions, such as sub-Saharan Africa (48%), North America (38%), and Asia-Pacific (33%). Participants in European studies were more likely to access daily and nondaily regimen options, which also resulted in a lower rate of PrEP discontinuation when compared with the offer of only a daily regimen [6]. However, the 6 European studies accounted for a minority of all studies in the meta-analysis, underscoring the need for further research to explore and understand factors contributing to PrEP persistence in this setting.

Persistence and retention are often used interchangeably in PrEP studies to describe consistent attendance to clinic visits [9-13]. While this definition is widely accepted, it has limitations in accurately describing PrEP use patterns over time. For instance, some individuals may attend regular PrEP visits but not consistently use the medication, while others may occasionally miss certain visits without disengaging from PrEP care [10, 11]. This situation is particularly applicable to on-demand PrEP users, who may need fewer PrEP refill visits as compared with daily users. To address these limitations and provide a more nuanced description of PrEP use, a broader concept of engagement in care can be useful for defining different trajectories and attitudes toward PrEP care over time based on diverse factors such as attendance to clinic visits, PrEP refills, and/or treatment adherence. Although PrEP initiations can be easily tracked by public health agencies, measuring engagement in PrEP care remains a challenge despite its major importance for PrEP effectiveness. Thus, well-designed prospective cohorts with regular follow-up and monitoring of participants remain crucial for accurately measuring PrEP starts and stops, understanding patterns of engagement over time, and identifying associated factors.

In this study, we took advantage of the data collected as part of the ANRS PREVENIR study, a large cohort of daily and ondemand PrEP users in the Paris region, to evaluate the engagement in PrEP care of gay, bisexual, and other men who have sex with men (GBMSM) during the first year after their enrollment in the study.

## **METHODS**

## **Participants and Data Collection**

The ANRS PREVENIR study, launched on 3 May 2017, is an ongoing prospective cohort study of PrEP implementation at 26 sites in the Paris region, France. All the study procedures were described in the original article [14]. Briefly, participants enrolled in the study were HIV negative (aged ≥18 years) at high risk of HIV infection who initiated PrEP (naive at enrollment) or continued PrEP (experienced) according to French guidelines. The prescribed PrEP regimen was a fixed-dose

combination of oral tenofovir disoproxil and emtricitabine (245 and 200 mg/pill, respectively), since oral PrEP has been fully subsidized in France since January 2016. Men and transgender women who have sex with men could choose between daily or on-demand PrEP and were allowed to switch between these regimens during the study. Participants followed the dosing regimen used in the IPERGAY trial for on-demand PrEP, also known as PrEP 2-1-1 [15]. Study visits were scheduled at enrollment, 1 month later for participants who were PrEP naive at enrollment, and then every 3 months thereafter. At each study visit, all participants systematically received a 3-month PrEP prescription of TDF/FTC (tenofovir disoproxil/emtricitabine), regardless of their PrEP dosing regimen. This prescription allowed them to pick up a box containing 30 TDF/FTC tablets from the pharmacy of their choice, every month for 3 months. Participants who temporarily stopped PrEP did not receive a PrEP prescription until their next visit. Sociodemographics and behavioral data, as well as PrEP prescriptions, were collected at each visit with an electronic case report form. Participants were also asked to complete at home a computer-assisted structured interview before each visit to collect additional information about education level, financial situation, alcohol and recreational drug use, and sexual behavior. To assess the perception of PrEP-related stigma, participants were asked in the self-administered questionnaire to indicate whether they considered that taking PrEP could give others a negative image of them (possible answers were "totally disagree," "mostly disagree," "mostly agree," and "totally agree"). The protocol of the ANRS-PREVENIR study was approved by the French Drug Agency (Agence nationale de sécurité du médicament et des produits de santé) and by the CPP Paris Ile de France IV ethics committee. All participants provided written informed consent. The study is registered with ClinicalTrials.gov (NCT03113123) and EudraCT (2016A0157744).

### **Study Outcomes**

We defined 4 categories of engagement in PrEP care based on attendance to study visits and PrEP prescription refills over the first year. (1) High engagement was defined as consistently attending scheduled visits at months 3, 6, 9, and 12 and receiving a PrEP prescription at each of these visits, including the baseline visit. (2) Low engagement in PrEP care referred to participants still being on follow-up at month 12 who either missed 1 or more study visits at months 3, 6, 9, and 12 or did not receive a PrEP refill prescription after attending 1 of these visits. (3) Disengagement in PrEP care referred to participants who permanently discontinued PrEP at any time during the first year. (4) Lost to follow-up included participants who missed 2 consecutive visits and were no longer followed at 12 months despite multiple contact attempts by the study team.

## **Statistical Analysis**

This analysis was restricted to cisgender GBMSM from the ANRS PREVENIR study (99% of study participants) who met the study inclusion criteria, initiated or continued PrEP at the baseline visit, and completed at least 1 follow-up visit. Participants who enrolled after 28 February 2019 were excluded from the analysis because they could not attend the month 12 visit due to the COVID-19 lockdown in March 2020. We a posteriori classified study participants into 3 groups: "daily" for those who consistently reported using daily PrEP at all study visits up to 12 months or until their last follow-up visit; "on demand" for those who consistently reported using on-demand PrEP at all study visits up to 12 months or until their last followup visit; and "switches" for those who alternated between periods of on-demand and daily PrEP use and thus did not fit exclusively into the on-demand or daily group. After describing engagement in PrEP care over the first-year visits in all participants according to the categories previously described, we analyzed factors associated with high engagement using univariable and multivariable logistic regression. The variables that we studied were as follows:

- Sociodemographic data: age, place of birth, educational level, financial situation
- PrEP use: experienced or not, PrEP regimen during the first year, and counseling at inclusion
- Perception of PrEP-related stigma: "PrEP can make you look bad/give you a negative image"—totally disagree and mostly disagree = "no" vs mostly agree and totally agree = "yes"
- Sexual behavioral data: regular sexual partner, number of partners in the past 3 months, number of condomless anal sex acts in the previous 4 weeks, condom and substance use during the last intercourse
- Prior use of postexposure prophylaxis, bacterial sexually transmitted infection (STIs) in the past year, and history of psychiatric event

All variables with a *P* value <.20 in univariable models were included in the multivariable model. Some data were missing—in particular, data collected as part of self-administered questionnaires. We used multiple imputations to replace them, creating 5 data sets in which missing data were imputed from the participants' other covariables, including the outcome, and combining the results with Rubin's rules. In addition, we performed 2 sensitivity analyses: (1) restricting the analysis to participants with complete data and (2) using consistent attendance at scheduled visits at months 3, 6, 9, and 12 as the sole criterion to define high engagement in PrEP care. Analyses were conducted with Stata/SE (version 13.0; StataCorp) and SAS (version 9.4; SAS Institute). All *P* values and 95% CIs were 2-sided, with a significance level set at .05.

#### **RESULTS**

Out of 3211 participants enrolled in the ANRS PREVENIR study, 2685 fulfilled the inclusion criteria for the present analysis. Figure 1 depicts the participant selection process for inclusion in this analysis. Of the 2685 participants included in the analysis, the median age was 36 years (IQR, 29-44). The majority of participants were born in France (83.5%), while a smaller proportion were born in other European countries (4.7%), the Americas (4.8%), Africa (3.5%), and Asia or Oceania (3.5%). A high proportion of participants (86.3%) had a university degree, and 70.9% reported a self-assessed comfortable financial situation. At baseline, 52.4% of participants were already undergoing PrEP, with a median duration of 9.7 months, and 51.5% had a bacterial STI in the previous 12 months. The median number of sexual partners in the previous 3 months was 10 (IQR, 5-20), and the median number of condomless anal sex acts in the previous 4 weeks was 2 (IQR, 0-5). One-third of study participants perceived PrEP-related stigma. Of the 2685 participants, 930 (34.6%) were classified as daily PrEP users, 919 (34.2%) as on-demand PrEP users, and 863 (31.1%) were classified in the switches group. The participants' characteristics by PrEP regimen are described in Table 1.

The cumulative proportion of participants with high engagement in PrEP care decreased from 86.0% at month 3 to 60.0% at month 12. Figure 2 displays the cumulative proportion of participants at 12 months and by visits according to the categories of engagement in PrEP care. At month 12, 438 study participants (16.3%) exhibited low engagement in PrEP care, 459 (17.1%) disengaged in PrEP care, and 176 (6.6%) were lost to follow-up. Table 2 provides a detailed description of the participants within each of these categories by PrEP dosing regimen used during the first year. One case of breakthrough HIV infection was documented in a participant who disengaged from PrEP care.

Several factors were significantly associated with high engagement in PrEP care at 12 months in multivariable analysis (Table 3). Age was positively correlated with engagement, with older participants being more likely to have high engagement, ranging from 47.3% in those aged 18 to 25 years to 68.0% in those aged ≥50 years (odds ratio [OR], 0.43; 95% CI, .29-.63; P < .001). Participants who enrolled earlier in the study were also more likely to be engaged, with 62.9% of those enrolled in 2017 having high engagement, as compared with 54.6% of those enrolled in 2019 (OR, 0.70; 95% CI, .54-.92; P = .04). Participants born in Europe had higher engagement rates than those born elsewhere, with engagement rates of 61.1% and 51.7% (OR, 0.73; 95% CI, .57-.94; P = .01). Individuals with a master degree or higher diploma had higher engagement in PrEP care (61.6%) when compared with those whose highest degree is a high school diploma (54.4%; OR, 1.35; 95% CI, 1.05-1.72; P = .05). Participants who were already undergoing PrEP

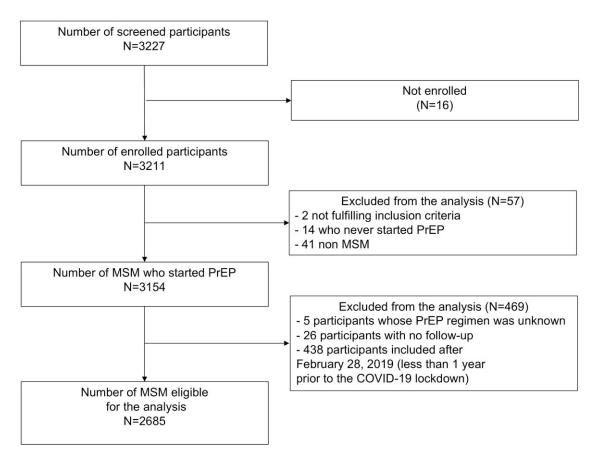


Figure 1. Flowchart of the participants included in the analysis. MSM, men who have sex with men; PrEP, preexposure prophylaxis.

at enrollment had higher engagement levels, with 67.0% of PrEP-experienced participants achieving high engagement as compared with 52.3% of those who were PrEP naive (OR, 1.77; 95% CI, 1.49–2.10, P < .0001). Participants who used daily PrEP the first year had higher engagement in PrEP care (64.0%) as compared with those who used on-demand PrEP (51.0%; OR, 0.54; 95% CI, .44–.65; P < .0001). Engagement in PrEP care was comparable between daily users (64.0%) and those who switched PrEP dosing regimens (65.5%) during the first year. Finally, participants with bacterial STIs in the last 12 months before enrollment were more likely to have high engagement in PrEP care (63.3% vs 56.6%; OR, 1.23; 95% CI, 1.04–1.45; P = .01).

Similar results were obtained when the analysis was restricted to the 2220 participants with complete data (Supplementary Table 1). High engagement in PrEP care was independently associated with older age, early enrollment in the study, prior experience of PrEP use, education level, history of bacterial STIs in the last 12 months, and daily PrEP use at baseline. Participants with a greater number of sexual partners tended to have higher engagement rates in PrEP care at 12 months in this sensitivity analysis (OR, 1.006; 95% CI, 1.000–1.011; P = .07). Finally, the same results were observed when high

engagement in PrEP care was defined solely by consistent attendance at scheduled visits at months 3, 6, 9, and 12, whether with imputed or complete patient data (Supplementary Tables 2 and 3).

#### **DISCUSSION**

In the French ANRS PREVENIR cohort study, GBMSM demonstrated relatively good engagement in PrEP care in the year after their enrolment. Almost two-thirds of participants consistently attended all study visits and received a PrEP prescription. Only one-quarter of participants disengaged from PrEP care or were lost to follow-up during this period. High engagement in PrEP care was associated with several factors: older age, being born in Europe, a recent history of bacterial STIs, earlier enrollment in the study, already undergoing PrEP, or exclusively using daily PrEP. Most of these associated factors reflect an increased perceived risk of HIV infection, emphasizing the critical role of HIV risk perception in PrEP care engagement.

Comparing PrEP persistence across studies is challenging due to the wide variation in definitions used. In our study, about onequarter of study participants discontinued PrEP or were lost to

Table 1. Characteristics of Participants at Baseline by First-Year PrEP Dosing Regimen

	No. (%) or Median (IQR)					
Characteristic	All	Daily	On Demand	Switches		
Participants	2685 (100)	930 (34.6)	919 (34.2)	863 (31.1)		
Age, y	36 (29-44)	35 (29-42)	37 (30–45)	35 (29-43)		
18–24	205 (7.7)	78 (8.4)	57 (6.2)	70 (8.4)		
25–29	508 (18.9)	181 (19.5)	162 (17.6)	165 (19.7)		
30–39	953 (35.5)	334 (35.9)	312 (34.0)	307 (36.7)		
40–49	707 (26.3)	245 (26.3)	259 (28.2)	203 (24.3)		
≥50	312 (11.6)	92 (9.9)	129 (14.0)	91 (10.9)		
Country of birth						
France <sup>a</sup>	2239 (83.5)	754 (81.3)	778 (84.8)	707 (84.6)		
America	128 (4.8)	59 (6.3)	31 (3.4)	38 (4.5)		
Europe	125 (4.7)	48 (5.2)	38 (4.1)	39 (4.7)		
Africa	95 (3.5)	33 (3.6)	38 (4.1)	24 (2.9)		
Asia/Oceania	94 (3.5)	33 (3.6)	33 (3.6)	28 (3.3)		
Missing	4			, ,		
Place of residence						
Paris	1553 (67.6)	526 (67.1)	520 (67.3)	507 (68.6)		
Outside Paris, Ile-de-France region	699 (30.5)	248 (31.6)	233 (30.1)	218 (29.5)		
Outside lle-de-France region	44 (1.9)	10 (1.3)	20 (2.6)	14 (1.9)		
Missing	389	10 (1.0)	20 (2.0)	11(1.0)		
Highest education level	303					
High school diploma	318 (13.7)	132 (16.6)	86 (11.0)	100 (13.5)		
2-y university degree or higher						
	846 (36.5)	286 (36.0)	282 (36.0)	278 (37.5)		
Master degree or higher	1155 (49.8)	376 (47.4)	415 (53.0)	364 (49.0)		
Missing	366	000 (07.4)	004 (07.4)	04.0 (00.0)		
Employment	1988 (85.9)	688 (87.1)	684 (87.4)	616 (83.2)		
Missing	372					
Financial situation	4044 (70.0)	5.45 (00.0)	507 (75.0)	500 (00.0)		
Comfortable	1641 (70.9)	545 (68.9)	587 (75.0)	509 (68.9)		
Difficult	672 (29.1)	246 (31.1)	196 (25.0)	230 (31.1)		
Missing	372					
Year of enrollment	/	/				
2017	895 (33.3)	293 (31.5)	318 (34.6)	284 (34.0)		
2018	1475 (55.0)	507 (54.5)	502 (54.6)	466 (55.7)		
2019 (until March)	315 (11.7)	130 (14.0)	99 (10.8)	86 (10.3)		
Psychiatric or depression history	372 (13.9)	131 (14.1)	108 (11.8)	133 (15.9)		
Ever used PEP	1048 (39.1)	364 (39.2)	362 (39.7)	322 (38.5)		
Missing	7					
Bacterial STIs in the past 12 mo <sup>b</sup>	1382 (51.5)	502 (54.0)	430 (46.8)	450 (53.9)		
Missing	1					
Regular sexual partner	1229 (45.8)	420 (45.2)	420 (45.8)	389 (46.5)		
Missing	2					
No. of partners in the last 3 mo before enrollment	10 (5–20)	15 (6–25)	10 (4–15)	10 (6–20)		
Missing	19					
No. of condomless anal sex acts in the prior month before enrollment	2 (0-5)	2 (0-6)	2 (0-4)	2 (0-5)		
Missing	90					
Condom use during the last sexual intercourse	970 (36.1)	346 (37.2)	318 (34.6)	306 (36.6)		
Use of psychoactive drugs during the last sexual intercourse <sup>c</sup>	379 (14.1)	131 (14.1)	126 (13.7)	122 (14.6)		
Already undergoing PrEP at enrollment	1408 (52.4)	493 (53.0)	497 (54.1)	418 (50.0)		
Time of PrEP, mo	9.7 (3.4–17.7)	9.7 (3.2-17.0)	10.6 (3.9-18.4)	8.9 (3.2–17.1)		
Risk reduction counseling by a peer community member or specialized nurse						
Accepted	2119 (79.5)	715 (77.5)	737 (80.8)	667 (80.4)		
Refused	375 (14.1)	143 (15.5)	115 (12.6)	117 (14.1)		
Not offered	171 (6.4)	65 (7.0)	60 (6.6)	46 (5.5)		
Missing data	20	* -*	** **			

Table 1. Continued

		No. (%) or Median (IQR)					
Characteristic	All	Daily	On Demand	Switches			
Perception of PrEP-related stigma	755 (32.8)	240 (30.5)	254 (32.7)	261 (35.5)			
Missing	384						

Abbreviations: PEP, postexposure prophylaxis; PrEP, preexposure prophylaxis; STI, sexually transmitted infection.

<sup>&</sup>lt;sup>c</sup>Psychoactive drugs used for sex include ecstasy, crack, and cocaine.

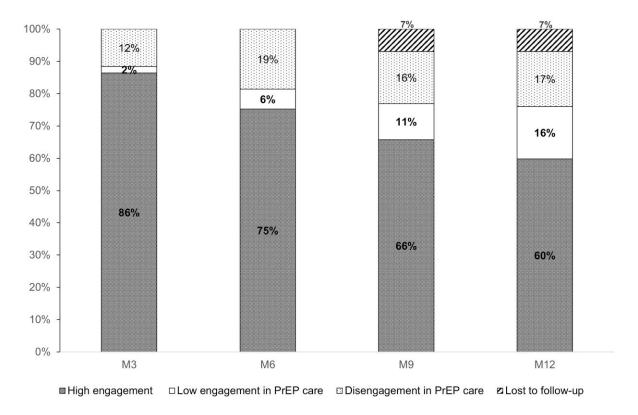


Figure 2. Categories of engagement in PrEP care: cumulative proportion at 12 months and by study visit. Baseline: N = 2685 participants. PrEP, preexposure prophylaxis.

follow-up during the first year, which aligns with the lowest discontinuation rates reported in early PrEP demonstration projects, such as those in Australia and Brazil [2, 16]. At the European level, this rate remains concordant with the pooled analysis of 6 European studies and the recent findings of another PrEP study in the Paris region [6, 17]. Similarly, the French National Health Data System (SNDS) showed that 20% of the 40 000 individuals who initiated PrEP in France between 2016 and 2021 discontinued it within the first 6 months [18].

Our study identified multiple factors that contribute to engagement in PrEP care. First, we found a strong correlation between younger age and less engagement in PrEP care at month 12. This finding has been reported in previous research [9, 11, 13, 19, 20] and is confirmed by the data from the SNDS showing

that PrEP effectiveness is significantly reduced in people younger than 30 years due to a high rate of PrEP discontinuation and adherence challenges [8]. To effectively engage young people in PrEP care and promote medication adherence and persistence over time, tailored interventions are crucial. Mobile health technology has demonstrated significant success in reaching, engaging, and supporting young individuals in PrEP care [21–23]. The broader implementation of this new technology, as well as the use of long-acting injectable PrEP options such as cabotegravir or lenacapavir, may contribute to reducing the PrEP gap in this group [24–26].

Apart from a younger age, participants born outside of Europe demonstrated lower engagement in PrEP care at 1 year. GBMSM born abroad remain disproportionately

<sup>&</sup>lt;sup>a</sup>Includes French overseas departments and territories.

<sup>&</sup>lt;sup>b</sup>Bacterial STIs include syphilis, Neisseria gonorrhoeae, Mycoplasma genitalium, and Chlamydia trachomatis

Table 2. Reasons for Not Achieving High Engagement in PrEP Care at 12 Months by First-Year PrEP Dosing Regimen

	PrEP Users, No. (%)				
	Total (n = 1073)	Daily (n = 335)	On Demand (n = 450)	Switch (n = 288)	
Low engagement in PrEP care	438 (40.8)	111 (33.1)	169 (37.6)	158 (54.9)	
One missing follow-up visit	291	81	116	94	
Two missing follow-up visits	68	14	24	30	
No PrEP prescription refill at least 1 visit	79	16	29	34	
Disengagement in PrEP care	459 (42.8)	150 (44.8)	183 (40.7)	126 (43.7)	
Did not feel at risk of HIV infection	36	12	13	11	
Participants no longer wished to participate	11	6	4	1	
Adverse events	4	2	1	1	
HIV infection	1	1	0	0	
Constraints	1	0	1	0	
Relocation	35	12	13	10	
Deaths	1	0	0	1	
Unknown reasons	370	117	151	102	
Lost to follow-up	176 (16.4)	74 (22.1)	98 (21.8)	4 (1.4)	

Abbreviation: PrEP, preexposure prophylaxis

affected by the HIV epidemic in France, accounting for 12% of all new HIV infections in 2021, with almost two-thirds occurring postmigration [27, 28]. Data on PrEP uptake among migrant GBMSM are scarce. From 2016 to 2023, the SNDS estimated that <0.5% of PrEP users in France benefited from the health government medical aid (Aide Médicale d'Etat) dedicated to undocumented people, which suggests a significant PrEP gap among migrants settling in France [29]. Interestingly, our results reveal that disparities in PrEP engagement persist even when non-European migrants are successfully linked to PrEP care. Multiple factors may contribute to the lower engagement in PrEP care observed in this group: language barriers, difficulty navigating the health care system, distinct social networks and support systems, different perceptions of HIV risk and prevention methods, or fear of being stigmatized when using PrEP. Addressing these complex and interrelated factors requires tailored interventions to reduce HIV transmission in this population.

Participants who reported riskier sexual behavior of HIV infection were more likely to demonstrate high engagement in PrEP care. Indeed, a greater number of condomless anal sex acts in the last month or sexual partners in the last 3 months, no condom use during the last sexual intercourse, or a history of bacterial STIs in the previous year were associated with higher engagement in PrEP care in univariable analysis. Despite the strong correlation between these variables, a history of bacterial STIs in the last 12 months and the number of sexual partners in the previous 3 months in the sensitivity analysis persisted as factors associated with high engagement in PrEP care. This association has been rarely highlighted in previous studies where sexual risk behaviors of HIV acquisition were partially explored [9, 10, 13, 19, 20, 30, 31]. This suggests that individuals who

engage in riskier sexual behavior have an accurate perception of the risk of HIV acquisition that supports their engagement in PrEP care. This result may be linked to the high education level in the cohort, with half of the study participants having a master degree or higher diploma. As reported in previous studies [9], having a higher education level was independently associated with high engagement in PrEP care in our analysis.

Distinct patterns of engagement in PrEP care emerged according to the PrEP dosing regimen used in the first year. Thus, PrEP users who exclusively used daily PrEP demonstrated higher engagement in PrEP care when compared with those who exclusively used on-demand PrEP. However, high engagement in PrEP care remained similar between daily PrEP users and participants who switched between regimens in the first year. Participants who used daily PrEP during the first year reported a higher number of sexual partners in the previous 3 months and more bacterial STIs in the past 12 months at baseline, 2 factors associated with higher engagement in PrEP in our analysis. An alternative explanation for this difference is that on-demand PrEP users can accumulate unused PrEP refill prescriptions over time, which could influence their attendance at study visits. Indeed, participants who chose on-demand PrEP used a median 12 pills (IQR, 4-16) per month, meaning that a 3-month PrEP prescription allowed them to have sufficient pills to be protected for up to 6 to 9 months [14]. This could explain the greater proportion of ondemand PrEP users in the low engagement PrEP care group, while their proportion tended to be lower to daily users among participants who disengaged from care. Considering that PrEP care involves more than just PrEP delivery—including regular HIV and STI testing, safety monitoring, and risk reduction counseling—it seems relevant to classify these patients as part

Table 3. Factors Associated With High Engagement in PrEP Care at 12 Months

	Participants, No. (%) or Mean (IQR)		Univariable Analysis		Multivariable Analysis	
		High Engagement in				
	Overall	PrEP Care at				
Characteristic	(n = 2685)	12 mo (n = 1612)	<i>P</i> Value	OR (95% CI)	<i>P</i> Value	OR (95% CI)
Age, y						
18–25	205	97 (47.3)	<.0001	0.42 (.30–.61)	<.0001	0.43 (.29–.63)
≥25 to < 30	508	265 (52.2)		0.51 (.38–.69)		0.51 (.38–.70)
≥30 to <40	953	571 (59.9)		0.71 (.54–.92)		0.67 (.51–.89)
≥40 to < 50	707	467 (66.1)		0.92 (.69–1.22)		0.87 (.65–1.17)
≥50	312	212 (68.0)		1		1
Inclusion period						
2017 (from May 3)	895	563 (62.9)	.03	1	.04	1
2018	1475	877 (59.3)		0.87 (.73–1.02)		0.94 (.78–1.12)
2019 (to Feb 28)	315	172 (54.6)		0.71 (.55–.92)		0.70 (.54–.92)
Country of birth <sup>a</sup>						
France + Europe	2368	1448 (61.1)	.0014	1	.01	1
Other	317	164 (51.7)		0.68 (.54–.86)		0.73 (.56–.94)
Highest educational level <sup>a</sup>						
High school diploma	375	204 (54.4)	.08	1	.05	1
2-y university degree or higher	981	590 (60.1)		1.22 (.94-1.60)		1.24 (.97–1.60)
Master degree or higher	1329	818 (61.6)		1.30 (1.03–1.64)		1.35 (1.05–1.72)
Comfortable financial situation <sup>a</sup>						
No	782	437 (55.9)	.01	1	.08	1
Yes	1903	1175 (61.7)		1.26 (1.05–1.51)		1.19 (.99–1.42)
Already undergoing PrEP at enrollment						
No	1277	668 (52.3)	<.0001	1	<.0001	1
Yes	1408	944 (67.0)		1.86 (1.59-2.17)		1.77 (1.49–2.10)
First-year PrEP dosing regimen						
Daily	930	595 (64.0)	<.0001	1	<.0001	1
On demand	919	469 (51.0)		0.59 (.4971)		0.54 (.4465)
Switches	836	548 (65.5)		1.07 (.88–1.30)		1.07 (.87–1.31)
Risk reduction counseling by a peer community member or nurse <sup>a</sup>						
	170	OC (EE O)	26	0.05 / 60, 1.16)		
Not offered	172	96 (55.8)	.36	0.85 (.62–1.16)		
Offered, not accepted	378	236 (62.4)		1.11 (.88–1.39)		
Offered, accepted	2135	1280 (60.0)		1		
Regular sexual partner	1.450	004 (50.0)	40	4		
No	1456	864 (59.3)	.43	1		
Yes	1229	748 (60.9)		1.06 (.91–1.24)		
Use of psychoactive drugs during the last sexual intercourse <sup>b</sup>						
No	2306	1387 (60.2)	.77	1		
Yes	378	225 (59.4)	.,,	0.97 (.78–1.21)		
Condom use during the last sexual intercourse	0,70	220 (00.1)		0.07 (.70 1.21)		
No	1715	1053 (61.4)	.06	1	.66	1
Yes	970	559 (57.6)	.00	0.86 (.73–1.00)	.00	1.04 (.87–1.24)
Bacterial STIs in the past 12 mo <sup>c</sup>	370	000 (07.0)		0.00 (.70 1.00)		1.04 (.07 1.24)
No	1302	737 (56.6)	.0004	1	.01	1
Yes	1383	875 (63.3)	.0004		.01	1.23 (1.04–1.45)
No. of sexual partners in the last 3 mo before enrollment <sup>a</sup>	2685	10 (6–20)	.01	1.32 (1.13–1.54) 1.006 (1.001–1.010)	.31	1.003 (.998–1.007)
No. of condomless anal sex acts in the prior month before enrollment <sup>a</sup>	2685	2 (0–6)	.02	1.014 (1.002–1.026)	.37	0.994 (.981–1.007)
Ever used PEP <sup>a</sup>						
No	1633	981 (60.1)	.96	1		
Yes	1052	631 (60.0)	.00	0.99 (.85–1.17)		
Psychiatric or depression history	1002	301 (00.0)		0.00 0.00 1.177		
No	2313	1384 (59.8)	.60	1		
Yes	372	228 (61.3)	.00	1.06 (.85–1.33)		
100	372	220 (01.0)		1.00 (.00-1.00)		

Table 3. Continued

	Participants, No. (%) or Mean (IQR)		Univariable Analysis		Multivariable Analysis	
Characteristic	Overall (n = 2685)	High Engagement in PrEP Care at 12 mo (n = 1612)	<i>P</i> Value	OR (95% CI)	<i>P</i> Value	OR (95% CI)
Perception of PrEP-related stigma						
No	1798	1070 (59.5)	.43	1		
Yes	887	542 (61.1)		1.07 (.90–1.26)		

Abbreviations: OR, odds ratio; PEP, postexposure prophylaxis; PrEP, preexposure prophylaxis; STI, sexually transmitted infection.

of the low engagement category, even if they consistently use PrEP despite not attending visits.

High engagement in PrEP care was correlated with prior experience with PrEP use and early enrollment in the study. The ANRS PREVENIR studies began enrolling participants in 2017, 1 year after PrEP was fully subsidized in France. Therefore, it is plausible that the first participants enrolled in the study were highly informed and committed members of the GBMSM community for whom PrEP was eagerly awaited, which may have translated into higher engagement in care as compared with later adopters. It also makes sense that participants already familiar with the medication and its use showed higher engagement in PrEP care than naive PrEP users. The experienced PrEP participants additionally represent a selected population of users already persistently taking PrEP, having used it for a median 10 months prior to enrollment.

Our study has several limitations. First, we did not incorporate adherence as part of the PrEP care engagement definition. Assessing adherence is challenging for on-demand PrEP, since the concentration of tenofovir diphosphate in dried blood spots can give an estimate of the number of pills taken over the last 6 to 8 weeks but does not necessarily guarantee coverage of all sexual events for on-demand PrEP [32]. However, HIV incidence in the ANRS PREVENIR study was very low (1.1 cases/1000 person-years) and similar among on-demand and daily PrEP users, suggesting a high adherence to PrEP among participants, whatever the dosing regimen used [14]. Second, the population consisted of highly educated urban GBMSM with a relatively comfortable socioeconomic situation, which may have contributed to their high level of engagement in PrEP care. As a result, our findings may not be generalizable to other GBMSM with different living conditions. Third, we were not able to evaluate the engagement in PrEP care beyond 1 year due to the impact of the COVID-19 pandemic on participants' follow-up. Some baseline factors not correlated with PrEP engagement at 1 year may become relevant over a longer follow-up period. It would also have been valuable to evaluate whether low engagement in PrEP care over the first year results

in a higher risk of PrEP discontinuation afterward. In the coming years, it will be relevant to evaluate the impact of new PrEP agents—for example, long-acting injectable PrEP such as cabotegravir and lenacapavir—on PrEP care engagement using a similar definition. This will be addressed in France as part of the ANRS 0410s–CABOPrEP trial (NCT06273943). Fourth, some study participants were lost to follow-up with unknown PrEP usage, potentially affecting the study's findings. Despite these limitations, we think that our study provides valuable insights into engagement in PrEP care in a large cohort of individuals using daily and on-demand PrEP in Europe with important implications for the development of interventions to support PrEP engagement over time.

#### CONCLUSIONS

GBMSM enrolled in the French ANRS PREVENIR cohort study demonstrated relatively good engagement in PrEP care, with almost two-thirds of study participants consistently attending all study visits and receiving a PrEP refill during the first year. While people who exclusively used daily PrEP and had a history of bacterial STIs demonstrated a higher commitment in PrEP care, younger individuals, those born in non-European countries, those with a lower education level, and those who were PrEP naive had lower engagement rates, underscoring the need for tailored interventions to support and enhance PrEP care in these specific groups.

## **Supplementary Data**

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

#### Notes

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<sup>&</sup>lt;sup>a</sup>Number of missing values (which were imputed): 4 for place of birth, 369 for educational level, 375 for financial situation, 21 for counseling, 2 for regular sexual partner, 1 for bacterial STIs in the previous 12 months, 19 for number of sexual partners in the previous 3 months, 90 for the number of condomless sex acts in the previous 4 weeks, 7 for prior postexposure prophylaxis.

<sup>&</sup>lt;sup>b</sup>Psychoactive drugs used for sex included ecstasy, crack, cocaine, GHB (gamma hydroxybutyrate), MDMA (3,4-methylenedioxymethamphetamine), and mephedrone.

Bacterial STIs included syphilis. Neisseria gonorrhoeae. Mycoplasma genitalium, and Chlamydia trachomatis.

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Author contributions. D. C., G. L., L. A., J.-M. M. designed the study. G. L. wrote the first draft of the report. D. C., L. A., G. L. designed the analysis. D. C., G. L., L. A., J.-M. M. analyzed and reviewed the data. L. B. and M. S. M. coordinated the ANRS Prevenir study. B. S. and D. M. designed the study questionnaire and the counseling interventions. R. P., G. P., L. Slama, L. Surgers, C. D., M. O., H. M., J. P., D. H. V., J. G., and J.-M. M. took part in the study at their sites. All authors critically reviewed and approved the manuscript.

Data availability. Data requests may be submitted to the scientific committee of the ANRS PREVENIR study (by email to jean-michel.molina@aphp.fr) and must be approved by the French data protection authority, la Commission Nationale de l'Informatique et des Libertes. French law requires that everyone who wishes to access cohort data or clinical study data on humans must ask the French data protection authority for permission by completing a form that can be provided by Lambert Assoumou (lambert.assoumou@iplesp.upmc.fr). For further information, see https://www.cnil.fr/. The ANRS PREVENIR scientific committee will evaluate each proposal for compatibility with general objectives, ethical approval, and informed consent forms of the ANRS PREVENIR project and for potential overlap with ongoing work.

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